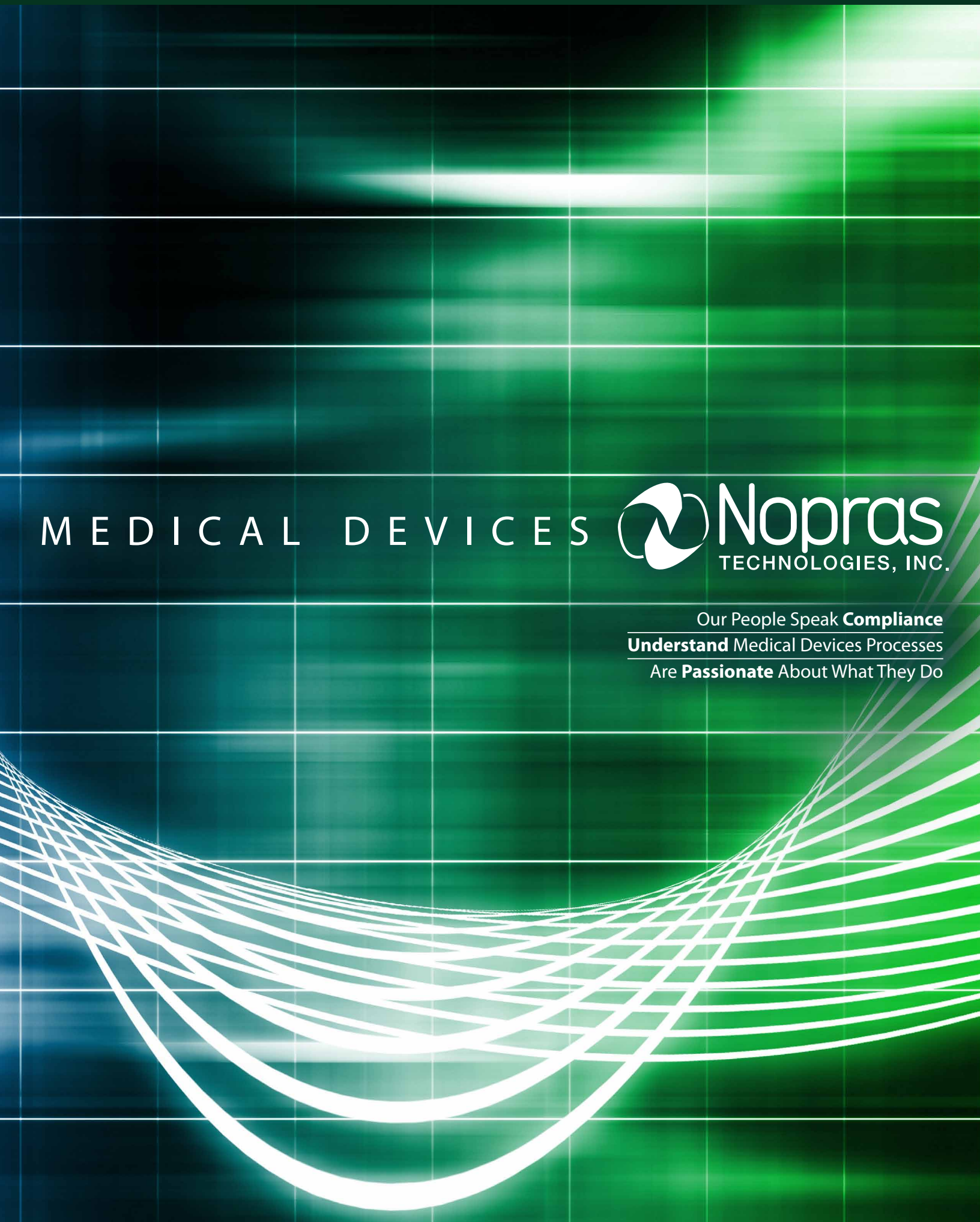
MEDICAL DEVICES
Nopras
TECHNOLOGIES, INC.
Our People Speak **Compliance**
Understand Medical Devices Processes
Are **Passionate** About What They Do

Nopras Technologies, Inc., is a full-service consulting company providing regulatory consulting services to the global pharmaceutical, biologics/biotechnology and medical device industries. Our staff includes experienced technical, quality, and compliance experts from industry leaders. The officers and employees of Nopras Technologies, Inc. offer a comprehensive knowledge of FDA and quality auditing procedures and practices and a unique awareness of regulatory enforcement policies and activities.

At Nopras Technologies, we believe that tremendous synergy comes from having experienced, senior level personnel from industry. Our experience also gives us a broad and detailed understanding of the complex business and compliance challenges faced by today's regulated companies.

MEDICAL DEVICES

Nopras
TECHNOLOGIES, INC.

With our extensive knowledge of the regulatory and compliance environment, we will enhance your competitive advantage while strengthening your bottom line. Nopras Technologies, Inc personnel average over 20 years of experience in product life cycle; from design, laboratory analysis, clinical development, through manufacturing and product tracking. Our proven risk-based approach to solving regulatory compliance issues is well-suited to the medical device industry.

Whether you are developing a new product, improving an existing product, or trying to comply with the numerous regulations and standards, Nopras Technologies will accelerate your success.

Our consulting services have been designed to address any areas involving regulatory or quality requirements as mandated by the FDA regulations and international standards, including *21 CFR 820, 21 CFR 1271, 21 CFR 11, and ISO 13485:2003.*

Nopras Technologies services for the Medical Devices Industry include:

- *Program Design*
- *Operational Excellence*
- *Regulatory Preparation and Submission*
- *Validation Consultation*
- *Operational Support*
- *Validation Protocol Development and Execution*

PROGRAM DESIGN

We support a team structure that is focused on the goals and milestones of our clients and achieved through close communication, detailed measurement and tracking. Nopras will build flexibility into your development strategy for risk mitigation and work with you to provide seamless communications.

- Preparing gap analysis
- Designing, executing and managing integrated development plans
- Controlling cost to agreed budgets

OPERATIONAL EXCELLENCE

In an ever changing marketplace, it takes consistency and discipline to keep everyone aligned. At Nopras Technologies, Inc, our Process Management Team will assist you to automate, manage and evolve processes to optimize performance and increase the bottom-line. From streamlining business activities contained within a single department to processes that cross your entire organization, our Process Management Team of experts will help your organization work smarter. We will help execute business processes with speed and consistency–ensuring that your organization doesn't just survive, it thrives.

- Operating Costs Reduction
- Capital Expenditure Minimization
- Scaling Production to Demand
- Production Efficiency Improvement and Cycle Time Reduction
- Quality Improvement
- Process Capability and Control (PC&C)
- Six Sigma Methodologies Implementation.

REGULATORY PREPARATION AND SUBMISSION

Nopras Technologies, Inc can guide you through the complicated regulatory environment associated with product development and registration. Our team of experts have extensive regulatory experience with the US FDA, EMEA, JPAL and Health Canada. We will assist you in making sound business decisions by providing proper understanding of the potential regulatory risks before they become major regulatory roadblocks. Our team of experts have a strategic regulatory focus with attention to the challenges in the pharmaceutical, medical device and biologic/biotechnology industries. Nopras Technologies team of experts employ critical thinking to identify and resolve problems in a proactive and innovative manner.

- Regulatory submission oversight, management, preparation & maintenance (U.S., Canada JPAL & E.U.)
- Development of Product Development Plan (PDP)
- Pre-IDE meeting preparation and post-meeting review
- CTA's or individual dossier components
- 510(k), 513(g), De Novo, Pre-IDE's, IDE's and PMA's
- Developing and implementing Quality Systems to meet applicable ISO 9000/ISO EN 9000 and ISO 13485/EN 46000 Series.
- Preparation of regulatory submission technical sections and summaries
- Regulatory compliance gap analysis of product development plans and submissions

DEVICE DEVELOPMENT SUPPORT

Our consultants offer a level of experience unmatched in the industry and provide exceptional process, technical, and regulatory support:

- Gap analysis & regulatory/scientific product assessment
- Strategic advice on development
- Guidance on interactions with regulatory agencies
- Technology transfer
- Method development
- Process development

Continued ►

VALIDATION CONSULTATION

- Design Review/Qualifications
- Validation Master Planning
- 21 CFR Part 11, Electronic Records/Electronic Signature Compliance
- Validation Implementation Planning
- Validation Policies and Procedures
- Validation Training
- cGMP/Quality Systems Auditing
- Quality Systems Design, Management, Remediation
- Stability Program Design/Implementation
- Software Supplier Audits
- Vendor Certification Process Design and Implementation

OPERATIONAL SUPPORT

- Metrology/Calibration System Development
- Standard Operating Procedures
- Preventative Maintenance Systems
- Change Control Development and Implementation

VALIDATION PROTOCOL DEVELOPMENT AND EXECUTION

Process Development and Validation

- Manufacturing Process Development and Validation
- Process Assessment and Optimization (Design of Experiments/SPC)
- Manufacturing Scale-Up
- Technology Transfer
- Technical Report Writing (Validation, etc.)
- Equipment Qualification
- Cleaning Validation

Computer Systems Validation

- Assessment and Remediation of Manufacturing, Laboratory, Medical Device, R&D Facilities & Equipment
- Computer-Controlled - Laboratory Equipment
- Database Management Systems (LIMS, ERP, MRP, MES, EMS, Documentation Management)
- IQ, OQ, PQ Protocols

Laboratory and Laboratory Support

- Method Development and Validation
- Cleaning Validation & Testing (Verification)
- Equipment Qualification (IQ, OQ, PQ)

Manufacturing and Manufacturing Support

- Cleaning Methods Development (Cleaning Validation)
- Sterilization Cycle Development
- Process Cycle Time Reduction
- Manufacturing Systems Design
- Packaging Process Design and Validation
- Documentation Systems Assessment and Remediation

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